

CLAIMS

1. A manifold system for biotechnology uses, comprising:
a manifold unit which is pre-sterilized and disposable so as to be adapted for single-time usage, including:

- (a) at least one length of tubing having at least one inlet end portion, at least one outlet end portion, an outside surface, and an inside surface which is sterilized for passage of a biotechnology fluid therethrough,
- (b) at least one single-use bag having a primary access port, and
- (c) an aseptic connector means for operatively connecting said length of tubing with said primary access port of the single-use bag; and

a plurality of pinch valves, at least one of which is remotely operable in response to a signal remote from said pinch valve, each said pinch valve engages said outside surface of the length of tubing at a discrete location therealong, each said pinch valve independently selectively allowing or stopping flow of the biotechnology fluid through said inside surface of the length of tubing at said discrete location for that pinch valve.

2. The manifold system in accordance with claim 1, wherein said primary access port of the single-use bag includes a shut-off clamp.

3. The manifold system in accordance with claim 1, wherein said single-use bag further includes access port means for releasing gas or pressure build-up from said bag.

4. The manifold system in accordance with claim 1, wherein said single-use bag further includes an auxiliary access port.

5. The manifold system in accordance with claim 1, wherein said single-use bag further includes access port means for releasing gas or pressure build-up from said bag and further includes an auxiliary access port.

6. The manifold system in accordance with claim 5, further including a shut-off clamp for said access port means and for said auxiliary access port.

7. The manifold system in accordance with claim 1, further including a single-use sterilizing filter positioned along said length of tubing such that the biotechnology fluid flows therethrough at a location upstream of said outlet end portion.

8. The manifold system in accordance with claim 1, wherein said system is for automated aseptic fluid transfer, wherein said outlet end portion of the tubing has a plurality of serially arranged outlet passageways having one of said aseptic connector means for operable connection with said single-use bag, and wherein each said pinch valve controls passage of the biotechnology fluid from the tubing to the single-use bag.

9. The manifold system in accordance with claim 8, further including a single-use sterilizing filter positioned along said length of tubing such that the biotechnology fluid flows therethrough at a location upstream of said outlet end portion.

10. The manifold system in accordance with claim 8, further including a disposable pressure sensor positioned along said length of tubing such that the biotechnology fluid flows

therethrough at a location upstream of said outlet end portion.

11. The manifold system in accordance with claim 9, further including a disposable pressure sensor positioned along said length of tubing such that the biotechnology fluid flows therethrough at a location downstream of said sterilizing filter and upstream of said outlet end portion.

12. The manifold system in accordance with claim 1, wherein said system is for automated preparative chromatography, wherein said tubing is in at least two sections including a chromatography feed section and a chromatographed fluid section, wherein said chromatography feed section has an outlet and a plurality of serially arranged inlet passageways having one of said aseptic connector means for operable connection with said single-use bag, wherein said chromatographed fluid section has an inlet and said outlet end portion of the tubing which has a plurality of serially arranged outlet passageways having one of said aseptic connector means for operable connection with said single-use bag, wherein said pinch valves control passage of the biotechnology fluid from said single-use bags to the chromatography feed section, and wherein another said pinch valve controls passage of the biotechnology fluid from the tubing chromatographed fluid section to the single-use bag of the chromatographed fluid section.

13. The manifold system in accordance with claim 12, further including a disposable pressure sensor positioned along said tubing chromatography feed section such that the biotechnology fluid flows therethrough at a location upstream of said outlet end portion.

14. The manifold system in accordance with claim 12, further including a chromatography column between said outlet of the chromatography feed section of the tubing and said inlet of the chromatographed fluid section of the tubing.

15. The manifold system in accordance with claim 1, wherein said system is for tangential flow filtration, wherein one said single-use bag is a process solution bag and another said single-use bag is a permeate collection bag, wherein said tubing is in at least two sections including a filtration flow-through section and a filtered fluid section, said filtration flow-through section includes said process solution bag, said filtered fluid section includes said permeate collection bag, and further including a disposable filter between said filtration flow-through section and said filtered fluid section, whereby fluid from said process solution bag is filtered through said disposable filter and is collected in said permeate collection bag.

16. The manifold system in accordance with claim 15, wherein said inlet end is within said filtration flow-through section and in operative communication with said process solution single-use bag, said filtration flow-through section further includes a recirculation length having one of said pinch valves between an exit port of said disposable filter and said process solution single-use bag, wherein another said pinch valve is positioned between said disposable filter and said permeate collection single-use bag.

17. The manifold system in accordance with claim 15, further including a disposable pressure sensor positioned along said filtration flow-through section tubing such that the biotechnology fluid flows therethrough at a location upstream of said disposable filter.

18. The manifold system in accordance with claim 15, further including a disposable pressure sensor positioned along said filtration flow-through section tubing such that the biotechnology fluid flows therethrough at a location between said disposable filter and said pinch valve.

19. The manifold system in accordance with claim 15, further including a disposable pressure sensor positioned along said filtered fluid length of tubing such that the biotechnology fluid flows therethrough at a location between said disposable filter and said permeate collection single-use bag.

20. A manifold system for biotechnology uses, wherein said system is for automated, aseptic fluid transfer, comprising: a manifold unit which is pre-sterilized and disposable so as to be adapted for single-time usage, including:

- (a) at least one length of tubing having at least one inlet end portion, at least one outlet end portion, an outside surface, and an inside surface which is sterilized for passage of a biotechnology fluid therethrough,
 - (b) a plurality of single-use bags, each having a primary access port,
 - (c) aseptic connector means for operatively connecting said length of tubing with said primary access port of at least one of said single-use bags, and
 - (d) said outlet end portion of the tubing has a plurality of serially arranged outlet passageways having one of said aseptic connector means for operable connection with said single-use bag; and
- a plurality of pinch valves, at least one of which is remotely operable in response to a signal remote from said pinch valve, each said pinch valve engages said outside

surface of the length of tubing at a discrete location therealong, each said pinch valve independently selectively allowing or stopping flow of the biotechnology fluid through said inside surface of the length of tubing at said discrete location for that pinch valve, and wherein each said pinch valve controls passage of the biotechnology fluid from the tubing to each said single-use bag.

21. The manifold system in accordance with claim 20, further including a single-use sterilizing filter positioned along said tubing such that the biotechnology fluid flows therethrough at a location upstream of said outlet passageways.

22. The manifold system in accordance with claim 20, further including a disposable pressure sensor positioned along said tubing such that the biotechnology fluid flows therethrough at a location upstream of said outlet passageways.

23. The manifold system in accordance with claim 21, further including a disposable pressure sensor positioned along said tubing such that the biotechnology fluid flows therethrough at a location downstream of said sterilizing filter and upstream of said outlet passageways.

24. The manifold system in accordance with claim 20, wherein said primary access port of the single-use bag includes a shut-off clamp.

25. The manifold system in accordance with claim 20, wherein said single-use bag further includes access port means for releasing gas or pressure build-up from said bag.

26. The manifold system in accordance with claim 20, wherein said single-use bag further includes an auxiliary access port.

27. The manifold system in accordance with claim 20, wherein said single-use bag further includes access port means for releasing gas or pressure build-up from said bag and further includes an auxiliary access port.

28. The manifold system in accordance with claim 27, further including a shut-off clamp for said access port means and for said auxiliary access port.

29. A manifold system for biotechnology uses, wherein said system is for automated preparative chromatography, comprising:

a manifold unit which is pre-sterilized and disposable so as to be adapted for single-time usage, including:

- (a) at least one length of tubing having at least one inlet end portion, at least one outlet end portion, an outside surface, and an inside surface which is sterilized for passage of a biotechnology fluid therethrough,
- (b) a plurality of single-use bags, each having an access port,
- (c) aseptic connector means for operatively connecting said length of tubing with said single-use bag,
- (d) said tubing is in at least two sections including a chromatography feed section and a chromatographed fluid section,
- (e) said chromatography feed section has an outlet and a plurality of serially arranged inlet passageways having one of said aseptic

connector means for operable connection with said single-use bag, and

(f) said chromatographed fluid section has an inlet, and said outlet end portion of the tubing is on the chromatographed fluid section and has a plurality of serially arranged outlet passageways having one of said aseptic connector means for operable connection with said single-use bag; and

a plurality of pinch valves, at least one of which is remotely operable in response to a signal remote from said pinch valve, each said pinch valve engages said outside surface of the length of tubing at a discrete location therealong, each said pinch valve independently selectively allowing or stopping flow of the biotechnology fluid through said inside surface of the length of tubing at said discrete location for that pinch valve, wherein said pinch valves control passage of the biotechnology fluid from said single-use bags to the chromatography feed section, and wherein another said pinch valve controls passage of the biotechnology fluid from the tubing chromatographed fluid section to the single-use bag of the chromatographed fluid section.

30. The manifold system in accordance with claim 29, further including a disposable pressure sensor positioned along said tubing such that the biotechnology fluid flows therethrough at a location upstream of said outlet passageways.

31. The manifold system in accordance with claim 29, further including a chromatography column between said outlet of the chromatography feed section of the tubing and said inlet of the chromatographed fluid section of the tubing.

32. The manifold system in accordance with claim 29, wherein at least one of said single-use bags further includes access port means for releasing gas or pressure build-up from said bag.

33. The manifold system in accordance with claim 29, wherein at least one of said single-use bags further includes an auxiliary access port.

34. The manifold system in accordance with claim 29, wherein at least one of said single-use bags further includes access port means for releasing gas or pressure build-up from said bag and further includes an auxiliary access port.

35. The manifold system in accordance with claim 34, further including a shut-off clamp for said access port, for said access port means, and for said auxiliary access port.

36. The manifold system in accordance with claim 29, further including a single-use sterilizing filter positioned along said tubing such that the biotechnology fluid flows therethrough at a location upstream of said outlet passageways.

37. A manifold system for biotechnology uses, wherein said system is for tangential flow filtration, comprising:

a manifold unit which is pre-sterilized and disposable so as to be adapted for single-time usage, including:

- (a) at least one length of tubing having at least one inlet end portion, at least one outlet end portion, an outside surface, and an inside surface which is sterilized for passage of a biotechnology fluid therethrough,

- (b) a plurality of single-use bags, each having an access port, one said single-use bag is a process solution bag and another said single-use bag is a permeate collection bag,
- (c) said tubing is in at least two sections including a filtration flow-through section and a filtered fluid section, said filtration flow-through section includes said process solution bag, said filtered fluid section includes said permeate collection bag,
- (d) an aseptic connector for operatively connecting said length of tubing with said single-use bag, and
- (e) a disposable filter between said filtration flow-through section and said filtered fluid section, whereby fluid from said process solution bag is filtered through said disposable filter and is collected in said permeate collection bag; and

a plurality of pinch valves, at least one of which is remotely operable in response to a signal remote from said pinch valve, each said pinch valve engages said outside surface of the length of tubing at a discrete location therealong, each said pinch valve independently selectively allowing or stopping flow of the biotechnology fluid through said inside surface of the length of tubing at said discrete location for that pinch valve.

38. The manifold system in accordance with claim 37, wherein said inlet end is within said filtration flow-through section and in operative communication with said process solution single-use bag, said filtration flow-through section further includes a recirculation length having one of said pinch valves between an exit port of said disposable filter and said

process solution single-use bag, wherein another said pinch valve is positioned between said disposable filter and said permeate collection single-use bag.

39. The manifold system in accordance with claim 37, further including a disposable pressure sensor positioned along said tubing such that the biotechnology fluid flows therethrough at a location upstream of said disposable filter.

40. The manifold system in accordance with claim 38, further including a disposable pressure sensor positioned along said recirculation length of tubing such that the biotechnology fluid flows therethrough at a location between said disposable filter and said pinch valve along said recirculation length.

41. The manifold system in accordance with claim 37, further including a disposable pressure sensor positioned along said filtered fluid length of tubing such that the biotechnology fluid flows therethrough at a location between said disposable filter and said permeate collection single-use bag.

42. The manifold system in accordance with claim 37, wherein said single-use bag further includes access port means for releasing gas or pressure build-up from said bag.

43. The manifold system in accordance with claim 37, wherein said single-use bag further includes an auxiliary access port.

44. The manifold system in accordance with claim 37, wherein said single-use bag further includes access port means for releasing gas or pressure build-up from said bag and further includes an auxiliary access port.

45. The manifold system in accordance with claim 44, further including a shut-off clamp for said access port, for said access port means, and for said auxiliary access port.

46. The manifold system in accordance with claim 37, further including a single-use sterilizing filter positioned along said tubing such that the biotechnology fluid flows therethrough at a location upstream of said outlet passageways.

47. A manifold and pump system for biotechnology uses, comprising:

a manifold unit which is pre-sterilized and disposable so as to be adapted for single-time usage, including:

- (a) at least one length of tubing having at least one inlet end portion, at least one outlet end portion, an outside surface, and an inside surface which is sterilized for passage of a biotechnology fluid therethrough,
- (b) at least one single-use bag having an access port, and
- (c) an aseptic connector means for operatively connecting said length of tubing with said access port of the single-use bag;

a plurality of pinch valves, at least one of which is remotely operable in response to a signal remote from said pinch valve, each said pinch valve engages said outside surface of the length of tubing at a discrete location therealong, each said pinch valve independently selectively allowing or stopping flow of the biotechnology fluid through said inside surface of the length of tubing at said discrete location for that pinch valve; and

a pump unit which engages said outside surface of the length of tubing at a selected location upstream of said discrete location for the pinch valve.

48. The manifold and pump system in accordance with claim 47, further including a controller which controls operation of said pump unit and of said pinch valve.

49. The manifold and pump system in accordance with claim 48, wherein said controller is a programmable unit.

50. The manifold and pump system in accordance with claim 48, wherein said controller is programmable and is included in said pump unit.

51. The manifold and pump system in accordance with claim 47, wherein said pinch valve is pneumatically operated.

52. The manifold and pump system in accordance with claim 47, wherein said pinch valve is electronically operated.

53. A manifold and pump system for biotechnology uses, wherein said system is for automated, aseptic fluid transfer, comprising:

a manifold unit which is pre-sterilized and disposable so as to be adapted for single-time usage, including:

- (a) at least one length of tubing having at least one inlet end portion, at least one outlet end portion, an outside surface, and an inside surface which is sterilized for passage of a biotechnology fluid therethrough,
- (b) a plurality of single-use bags, each having an access port,

- (c) aseptic connector means for operatively connecting said length of tubing with said access port of at least one of said single-use bags, and
- (d) said outlet end portion of the tubing has a plurality of serially arranged outlet passageways having one of said aseptic connector means for operable connection with said single-use bag;

a plurality of pinch valves, at least one of which is remotely operable in response to a signal remote from said pinch valve, each said pinch valve engages said outside surface of the length of tubing at a discrete location therealong, each said pinch valve independently selectively allowing or stopping flow of the biotechnology fluid through said inside surface of the length of tubing at said discrete location for that pinch valve, and wherein each said pinch valve controls passage of the biotechnology fluid from the tubing to each said single-use bag; and

a pump unit which engages said outside surface of the length of tubing at a selected location upstream of said discrete location for the pinch valve.

54. A manifold and pump system for biotechnology uses, wherein said system is for automated preparative chromatography, comprising:

a manifold unit which is pre-sterilized and disposable so as to be adapted for single-time usage, including:

- (a) at least one length of tubing having at least one inlet end portion, at least one outlet end portion, an outside surface, and an inside surface which is sterilized for passage of a biotechnology fluid therethrough,

- (b) a plurality of single-use bags, each having an access port,
- (c) aseptic connector means for operatively connecting said length of tubing with said single-use bag access port,
- (d) said tubing is in at least two sections including a chromatography feed section and a chromatographed fluid section,
- (e) said chromatography feed section has an outlet and a plurality of serially arranged inlet passageways having one of said aseptic connector means for operable connection with said single-use bag access port, and
- (f) said chromatographed fluid section has an inlet, and the chromatographed fluid section has and said outlet end portion of the tubing which has a plurality of serially arranged outlet passageways having one of said aseptic connector means for operable connection with said single-use bag;

a plurality of pinch valves, at least one of which is remotely operable in response to a signal remote from said pinch valve, each said pinch valve engages said outside surface of the length of tubing at a discrete location therealong, each said pinch valve independently selectively allowing or stopping flow of the biotechnology fluid through said inside surface of the length of tubing at said discrete location for that pinch valve, wherein said pinch valves control passage of the biotechnology fluid from said single-use bags to the chromatography feed section, and wherein another said pinch valve controls passage of the biotechnology fluid from the tubing chromatographed fluid section to the single-use bag of the chromatographed fluid section;

a chromatography column between said chromatography feed section and said chromatographed fluid section; and

a pump unit which engages said outside surface of the length of tubing at a selected location upstream of said chromatography column.

55. A manifold and pump system for biotechnology uses, wherein said system is for tangential flow filtration, comprising:

a manifold unit which is pre-sterilized and disposable so as to be adapted for single-time usage, including:

- (a) at least one length of tubing having at least one inlet end portion, at least one outlet end portion, an outside surface, and an inside surface which is sterilized for passage of a biotechnology fluid therethrough,
- (b) a plurality of single-use bags, each having an access port, one said single-use bag is a process solution bag and another said single-use bag is a permeate collection bag,
- (c) said tubing is in at least two sections including a filtration flow-through section and a filtered fluid section, said filtration flow-through section includes said process solution bag, said filtered fluid section includes said permeate collection bag,
- (d) an aseptic connector means for operatively connecting said length of tubing with said single-use bag, and
- (e) a disposable filter between said filtration flow-through section and said filtered fluid section, whereby fluid from said process solution bag is filtered through said

disposable filter and is collected in said permeate collection bag;

a plurality of pinch valves, at least one of which is remotely operable in response to a signal remote from said pinch valve, each said pinch valve engages said outside surface of the length of tubing at a discrete location therealong, each said pinch valve independently selectively allowing or stopping flow of the biotechnology fluid through said inside surface of the length of tubing at said discrete location for that pinch valve; and

a pump unit which engages said outside surface of the length of tubing at a selected location upstream of said disposable filter.

56. An automated manifold and pump system for biotechnology uses, comprising:

a manifold unit which is pre-sterilized and disposable so as to be adapted for single-time usage, including:

- (a) at least one length of tubing having at least one inlet end portion, at least one outlet end portion, an outside surface, and an inside surface which is sterilized for passage of a biotechnology fluid therethrough,
- (b) at least one single-use bag having an access port, and
- (c) an aseptic connector means for operatively connecting said length of tubing with said single-use bag;

a plurality of pinch valves, at least one of which is remotely operable, and each said pinch valve engages said outside surface of the length of tubing;

a pump unit which engages said outside surface of the length of tubing at a selected location upstream of said pinch valve; and

a controller which controls operation of said pump unit and of said pinch valve, said controller having control logic which dictates the timing of opening and closing of said remotely operable pinch valve.

57. The automated system in accordance with claim 56, wherein said control logic of the controller determines the extent of filling of the single-use bag by processing data monitored by the system to achieve filling of the single-use bag by volume, by weight, or by pump rate and filling time.

58. The automated system in accordance with claim 56, wherein said control logic of the controller dictates the rate of pumping of said pump unit.

59. An automated manifold and pump system for biotechnology uses, wherein said system is for automated, aseptic fluid transfer, comprising:

a manifold unit which is pre-sterilized and disposable so as to be adapted for single-time usage, including:

- (a) at least one length of tubing having at least one inlet end portion, at least one outlet end portion, an outside surface, and an inside surface which is sterilized for passage of a biotechnology fluid therethrough,
- (b) a plurality of single-use bags, each having an access port,
- (c) an aseptic connector for operatively connecting said length of tubing with said access port of at least one of said single-use bags, and
- (d) said outlet end portion of the tubing has a plurality of serially arranged outlet passageways having one of said aseptic

connectors for operable connection with said single-use bag;

a plurality of pinch valves, at least one of which is remotely operable, and each said pinch valve engages said outside surface of the length of tubing at a discrete location therealong and controls passage of the biotechnology fluid from the tubing to each said single-use bag;

a pump unit which engages said outside surface of the length of tubing at a selected location upstream of said discrete location for the pinch valve; and

a controller which controls operation of said pump unit and of said pinch valve, said controller having control logic which dictates the timing of opening and closing of said remotely operable pinch valve.

60. The automated system in accordance with claim 59, wherein said control logic of the controller dictates the rate of pumping of said pump unit.

61. The automated system in accordance with claim 59, wherein said control logic of the controller determines the extent of filling of the single-use bag by processing data monitored by the system to achieve filling of the single-use bag by volume, by weight, or by pump rate and filling time.

62. The automated system in accordance with claim 59, wherein said control logic activates pumping action of said pump unit and opens a first remotely operable pinch valve for a length of time needed to pump a selected volume or weight of biotechnology fluid into a first said single-use bag associated with said first remotely operable pinch valve, wherein said control logic activates pumping action of said pump unit and opens a second remotely operable pinch valve for a length of time needed to pump a selected volume or weight of

biotechnology fluid into a second said single-use bag associated with said second remotely operable pinch valve, and wherein said control logic activates pumping action of said pump unit and opens a further remotely operable pinch valve for a length of time needed to pump a selected volume or weight of biotechnology fluid into a further said single-use bag associated with said second remotely operable pinch valve until a user-selected number of single-use bags are filled.

63. The automated system in accordance with claim 59, wherein said control logic activates pumping action of said pump unit and opens a first remotely operable pinch valve for a length of time needed to pump a selected volume or weight of biotechnology fluid into a first said single-use bag associated with said first remotely operable pinch valve, and wherein said control logic activates pumping action of said pump unit and opens a further remotely operable pinch valve for a length of time needed to pump a selected volume or weight of biotechnology fluid into a further said single-use bag associated with said second remotely operable pinch valve until a user-selected number of single-use bags are filled.

64. An automated manifold and pump system for biotechnology uses, wherein said system is for automated preparative chromatography, comprising:

a manifold unit which is pre-sterilized and disposable so as to be adapted for single-time usage, including:

- (a) at least one length of tubing having at least one inlet end portion, at least one outlet end portion, an outside surface, and an inside surface which is sterilized for passage of a biotechnology fluid therethrough,
- (b) a plurality of single-use bags, each having an access port,

- (c) aseptic connector means for operatively connecting said length of tubing with said single-use bag,
- (d) said tubing is in at least two sections including a chromatography feed section and a chromatographed fluid section,
- (e) said chromatography feed section has an outlet and a plurality of serially arranged inlet passageways having one of said aseptic connector means for operable connection with said single-use bag, and
- (f) said chromatographed fluid section has an inlet and said outlet end portion of the tubing which has a plurality of serially arranged outlet passageways having one of said aseptic connector means for operable connection with said single-use bag;

a plurality of pinch valves, at least one of which is remotely operable, each said pinch valve engages said outside surface of the length of tubing at a discrete location therealong, each said pinch valve independently selectively allowing or stopping flow of the biotechnology fluid through said inside surface of the length of tubing at said discrete location for that pinch valve, wherein said pinch valves control passage of the biotechnology fluid from said single-use bags to the chromatography feed section, and wherein another said pinch valve controls passage of the biotechnology fluid from the tubing chromatographed fluid section to the single-use bag of the chromatographed fluid section;

a chromatography column between said chromatography feed section and said chromatographed fluid section;

a pump unit which engages said outside surface of the length of tubing at a selected location upstream of said chromatography column; and

a controller which controls operation of said pump unit and of said pinch valve, said controller having control logic which dictates opening and closing of said remotely operable pinch valve.

65. The automated system in accordance with claim 64, wherein said control logic of the controller dictates the rate of pumping of said pump unit.

66. The automated system in accordance with claim 64, wherein said control logic of the controller determines the extent of filling of the single-use bag by processing data monitored by the system to achieve filling of the single-use bag by volume, by weight, or by pump rate and filling time.

67. The automated system in accordance with claim 64, wherein said control logic has a loading cycle which activates said pump unit and opens a first and a second said remotely operated pinch valve, said first pinch valve is upstream of said chromatography column and controls egress of process solution from a container thereof, said second pinch valve is downstream of said chromatography column and controls access to a first said single-use bag; said loading cycle of the control logic precedes an elution cycle which opens a third said remotely operated pinch valve which is upstream of said chromatography column and controls egress of elution solution from a container thereof and into and through said chromatography column; and said control logic has a peak value collection cycle which activates a fourth said remotely operated pinch valve which is downstream of said chromatography column and controls access of said elution solution into a second said single-use bag.

68. The automated system in accordance with claim 67, wherein said control logic further includes at least one wash cycle during which said fourth remotely operated pinch valve is closed to deny access to said second single-use bag.

69. The automated system in accordance with claim 64, further including a detector downstream of said chromatography column which monitors flow out of said chromatography column for a peak collection value; and wherein said control logic receives peak collection value data from said detector for use in said peak value collection cycle.

70. An automated manifold and pump system for biotechnology uses, wherein said system is for tangential flow filtration, comprising:

a manifold unit which is pre-sterilized and disposable so as to be adapted for single-time usage, including:

- (a) at least one length of tubing having at least one inlet end portion, at least one outlet end portion, an outside surface, and an inside surface which is sterilized for passage of a biotechnology fluid therethrough,
- (b) a plurality of single-use bags, each having an access port, one said single-use bag is a process solution bag and another said single-use bag is a permeate collection bag,
- (c) said tubing is in at least two sections including a filtration flow-through section and a filtered fluid section, said filtration flow-through section includes said process solution bag, said filtered fluid section includes said permeate collection bag,

- (d) an aseptic connector means for operatively connecting said length of tubing with said single-use bag, and
- (e) a disposable filter between said filtration flow-through section and said filtered fluid section, whereby fluid from said process solution bag is filtered through said disposable filter and is collected in said permeate collection bag;

a plurality of pinch valves, at least one of which is remotely operable in response to a signal remote from said pinch valve, each said pinch valve engages said outside surface of the length of tubing at a discrete location therealong;

a pump unit which engages said outside surface of the length of tubing at a selected location upstream of said disposable filter; and

a controller which controls operation of said pump unit and of said pinch valve, said controller having control logic which dictates opening and closing of said remotely operable pinch valve.

71. The automated system in accordance with claim 70, wherein said control logic of the controller dictates the rate of pumping of said pump unit.

72. The automated system in accordance with claim 70, wherein said control logic of the controller determines the extent of filling of the single-use permeate collection bag by processing data monitored by the system to achieve filling of the single-use bag by volume, by weight, or by pump rate and filling time.

73. The automated system in accordance with claim 70, further including at least one detector positioned along a location downstream of said disposable filter for monitoring a parameter of the fluid within said tubing and for transmitting data on the parameter to the controller, wherein said control logic receives said data from said detector and monitors the flow of fluid through the filtration flow through section of the tubing until an optimal pump recirculation parameter is achieved, at which time said control logic signals that said filtration flow through section of the tubing is to be blocked by closing one of said pinch valves and signals that said filtered fluid section of the tubing is to be unblocked by opening another of said pinch valves, whereby filtered fluid begins to flow into said single-use permeate collection bag.

74. The automated system in accordance with claim 73, wherein said detector is a pressure sensor, wherein said pump recirculation parameter is fluid pressure, and wherein said control logic receives data from said pressure sensor to determine when said optimum pump recirculation pressure is achieved.

75. The automated system in accordance with claim 74, wherein said control logic directs the pump unit to modify its pumping rate in response to changes in pressure at the pressure sensor so as to maintain a substantially constant selected flow rate imparted to the fluid by the pump unit and thereby assist in achieving said optimum pump recirculation pressure.

76. The automated system in accordance with claim 73, wherein said detector is a fluid flow rate sensor, wherein said pump recirculation parameter is fluid velocity, and wherein said control logic receives data from said fluid flow rate sensor

to determine when said optimum pump recirculation fluid velocity is achieved.

77. The automated system in accordance with claim 76, wherein said control logic directs the pump unit to modify its pumping rate in response to changes in flow rate at said fluid flow rate sensor so as to maintain a substantially constant selected flow rate imparted to the fluid by the pump unit and thereby assist in achieving said optimum pump recirculation pressure.